DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 25, 2014

Kimberly-Clark Corp.
Charnelle Thomas
Global Regulatory Affairs Specialist
1400 Holcomb Bridge Road
Rowell, GA 30076

Re: K141294
Trade/Device Name: U by Kotex Security Unscented Menstrual Tampons
Regulation Number: 21 CFR§ 884.5470
Regulation Name: Unscented menstrual tampon
Regulatory Class: II
Product Code: HEB
Dated: June 17, 2014
Received: June 19, 2014

Dear Charnelle Thomas,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Kimberly-Clark Corporation

INDICATIONS FOR USE

Applicant:	Kimberly-Clark Corporation
510(k) Number:	K141294
Device Name:	Kimberly-Clark* U by Kotex® Security® Unscented Menstrual Tampons
Indications for Use:	Kimberly-Clark* U by Kotex® Security® is an unscented menstrual tampon inserted into the vagina to absorb menstrual fluid.

Prescription Use_____ OR Over-The-Counter ____**X**____
Per 21CFR 801.109 Subpart D Per 21CFR 801.109 Subpart C

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Kimberly-Clark Corporation

Traditional 510(k) for Kimberly-Clark* U by Kotex® Security®
Unscented Menstrual Tampons

Section 5. 510(k) SUMMARY

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Submitter's Name:	Kimberly-Clark Corporation
Submitter's Address:	2100 Winchester Road Neenah, WI 54956 **Mailing address for regulatory correspondence:** 1400 Holcomb Bridge Road Roswell, GA 30076-2199
Submitter's Phone No:	678-352-6031
Submitter's Fax No.	920-225-4979
Date of Preparation:	August 25, 2014
Name of Device Trade Name: Common Name: Classification Name: Product Code: Classification:	 U by Kotex® Security® Unscented Menstrual Tampons; Regular, Super and Super Plus absorbencies Menstrual Tampon, Unscented Tampon, Menstrual, Unscented HEB 21 CFR 884.5470
Predicate Device:	Kimberly-Clark* U by Kotex® Security® Unscented Menstrual Tampons K896994
Reference Device:	Kimberly-Clark* U by Kotex® Sleek® Unscented Menstrual Tampons K112635
Description of the device:	This device is a conventional unscented menstrual tampon consisting of an absorbent pledget, a withdrawal cord and an applicator. The absorbent pledget consists of a ribbon of rayon fibers and cotton, overwrapped with a non-woven fabric. A withdrawal cord is placed through the pledget and knotted. The tampon pledget is compressed. The formed pledget is inserted into a two-piece plastic applicator consisting of an inner tube (plunger), and an outer insertion tube (barrel) with flexible petals that form a closed, rounded tip. Each tampon is individually wrapped in a plastic film wrapper and multiple tampons are packaged in sealed cartons for commercial sale. Tampons are available in Regular, Super and Super Plus absorbencies in various counts.

Kimberly-Clark Corporation

Traditional 510(k) for Kimberly-Clark* U by Kotex® Security®
Unscented Menstrual Tampons

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION (Continued)

Indications for Use:	Kimberly-Clark* U by Kotex® Security® is an unscented menstrual tampon intended to be inserted into the vagina to absorb menstrual fluid.		
Summary of technological characteristics compared to the predicate device:	The device is the same as the predicate device with regards to the tampon component materials and overall design. The difference between the subject and predicate device applicator is in the addition of two new applicator colors, emerald green and royal blue. The subject device applicator is the same as the predicate device applicator in all other respects. There will also be minor changes to the brandname, packaging and labeling. The brandname will change from Kotex® Security® Natural Balance to U by Kotex® Security®.		
Brief description of preclinical toxicology: (biocompatibility) tests	Testing from the reference device, U by Kotex® Sleek® K112635, was used to support the safety of new applicator colors.		
	Preclinical Tests	**Standard**	**Performance**
	Genotoxicity Test (MLA)	ISO 10993, Part 3	Meets
	Genotoxicity Test (AMES)	ISO 10993, Part 3	Meets
	Genotoxicity Test (Mouse Micronucleus)	ISO 10993, Part 3	Meets
	Cytotoxicity Test	ISO 10993, Part 5	Meets
	Mucosal Irritation Test	ISO 10993, Part 10	Meets
	Mucosal Sensitization Test	ISO 10993, Part 10	Meets
	Acute Systemic Toxicity Test	ISO 10993, Part11	Meets
	Colorant Extraction Test	USP 661	Meets
Safety Assessment:	The subject 510(k) device has undergone an extensive series of safety tests, including an assessment of performance characteristics, preclinical microbiological testing and biocompatibility testing. Testing from the reference device, U by Kotex® Sleek® K112635, was used to support the safety of new applicator colors. The results of these studies support the conclusion that the subject 510(k) device is equivalent and as safe as the predicate device, the Kimberly- Clark* Kotex® Security® Tampon.		

Kimberly-Clark Corporation

Traditional 510(k) for Kimberly-Clark* U by Kotex® Security®
Unscented Menstrual Tampons

SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION (Continued)

Effectiveness:	Kimberly-Clark* U by Kotex® Security® Unscented Menstrual Tampons comply with the syngyna absorbency requirements of 21 CFR §801.430 as does the predicate device, the Kimberly-Clark* Kotex® Security® Tampon.
Conclusions:	The results of the extensive performance assessments, *in vitro* microbiological and biocompatibility testing of the subject device, Kimberly-Clark*U by Kotex® Security® Unscented Menstrual Tampons, support the conclusion that it is safe for its intended use and that it is substantially equivalent to the predicate device, the Kimberly- Clark* Kotex® Security® Tampon.